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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,117

09/12/2006

Craig Steven Harris

101401-IP US

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EXAMINER

RICCI, CRAIG D

ART UNIT

PAPER NUMBER

4161

MAIL DATE

DELIVERY MODE

08/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,117	Applicant(s) HARRIS, CRAIG STEVEN	
	Examiner CRAIG RICCI	Art Unit 4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

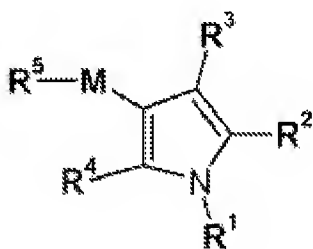
Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

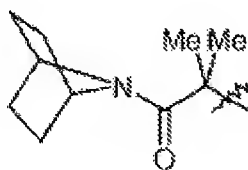
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 2-6, 8-12, 14 and 16 drawn to a compound of the formula



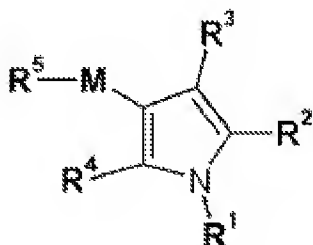
wherein R² is 3,5-dimethylphenyl-; R³ is Formula (IIa) or (IIb);



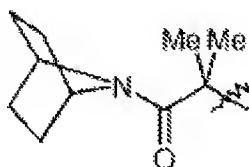
B is Formula (IV); and R⁵ is

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Group II, claim(s) 2-6, 8-11, 14 and 16 drawn to a compound of the formula

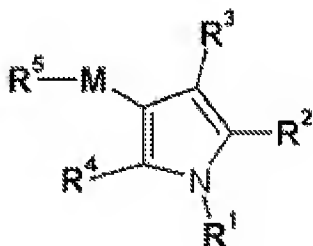


wherein R² is 3,5-dimethylphenyl-; R³ is Formula (IIa) or (IIb);

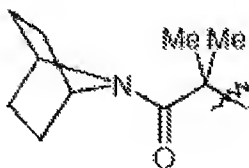


B is **not** Formula (IV); and R⁵ is

Group III, claim(s) 2-11, 14 and 16, drawn to a compound of the formula

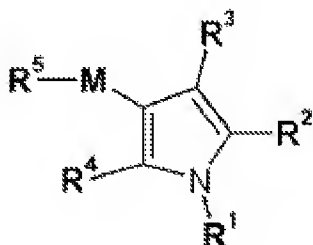
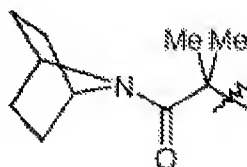
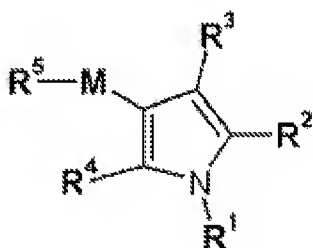
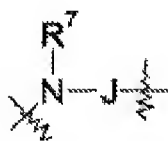


wherein R² is 3,5-dimethylphenyl-; R³ is Formula (IIc) or (IId);



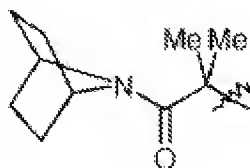
J is -(CH₂)_s-L-(CH₂)_s; and R⁵ is

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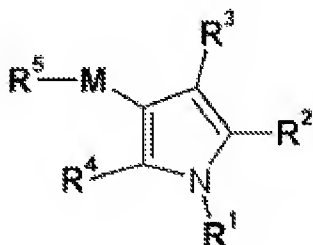
Group IV, claim(s) 2-11, 14 and 16 drawn to a compound of the formulawherein R² is 3,5-dimethylphenyl-; R³ is Formula (IIc) or (IId);J is $-(CH_2)_s-C(O)-(CH_2)_s-L-(CH_2)_s$; and R⁵ is**Group V**, claim(s) 2-11, 13-14 and 16, drawn to a compound of the formulawherein R² is 3,5-dimethylphenyl-; R³ is Formula (IIc) or (IId);

the group

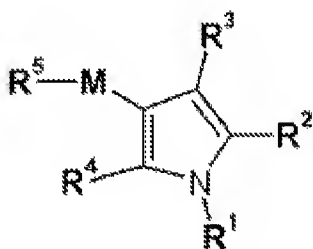
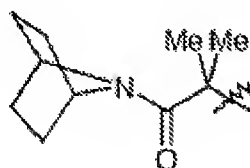
together forms an optionally substituted heterocyclic ring; and

R⁵ is

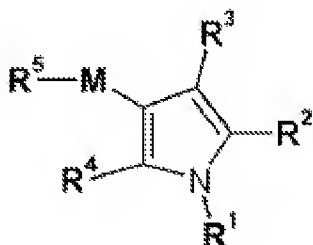
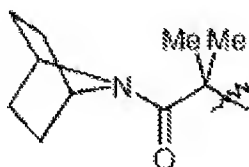
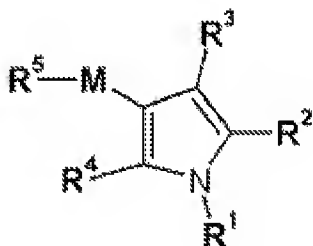
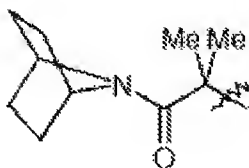
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Group VI, claim(s) 2-14, drawn to a compound of the formulawherein R², R³, and R⁵ are **not** defined as above for any

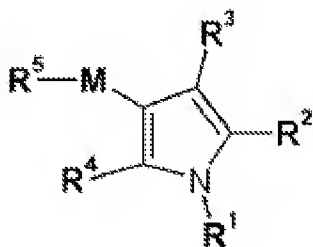
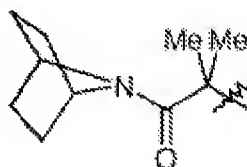
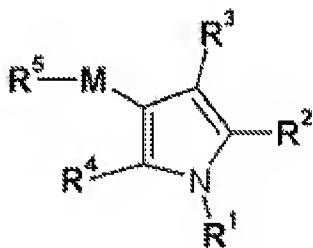
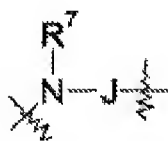
Groups I – V.

Group VII, claim(s) 1 drawn to a method of using the compound of the formulawherein R² is 3,5-dimethylphenyl-; R³ is Formula (IIa) or (IIb);B is Formula (IV); and R⁵ is

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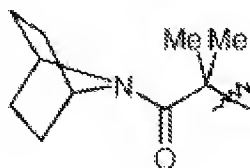
Group VIII, claim(s) 1 drawn to a method of using the compound of the formulawherein R² is 3,5-dimethylphenyl-; R³ is Formula (IIa) or (IIb);B is **not** Formula (IV); and R⁵ is**Group IX**, claim(s) 1, drawn to a method of using the compound of the formulawherein R² is 3,5-dimethylphenyl-; R³ is Formula (IIc) or (IId);J is -(CH₂)_s-L-(CH₂)_s; and R⁵ is

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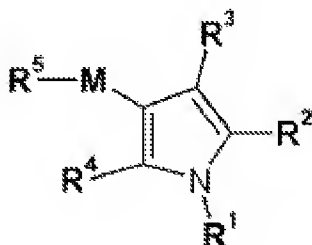
Group X, claim(s) 1 drawn to a method of using the compound of the formulawherein R^2 is 3,5-dimethylphenyl-; R^3 is Formula (IIc) or (IId);J is $-(CH_2)_s-C(O)-(CH_2)_s-L-(CH_2)_s$; and R^5 is**Group XI**, claim(s) 1, drawn to a method of using the compound of the formulawherein R^2 is 3,5-dimethylphenyl-; R^3 is Formula (IIc) or (IId);

the group

together forms an optionally substituted heterocyclic ring; and

 R^5 is

Group XII, claim(s) 1, drawn to a method of using the compound of the formula



wherein R², R³, and R⁵ are **not** defined as above for any

Groups VI – XI

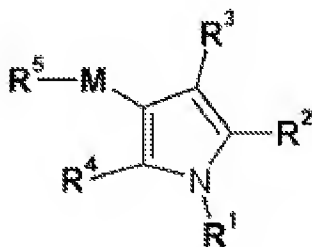
Group XIII, claim(s) 15, drawn to a method of making the inventions of Groups I-V.

Applicant is advised that Group VI, if elected, may be subject to further restriction.

2. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." Moreover, as stated in PCT Rule 13.2, "where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Furthermore, Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

3. The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups VI are drawn to compounds of the formula



wherein the variable groups R¹-R⁵ and M are defined in the claim. Given the substantial number of possibilities for each variable group R¹-R⁵ and M, including the possibility that each variable group can include additional variable groups which further can include even more variable groups and so on, it is clear that Group VI encompasses literally millions of potential compounds. As such, the only special technical feature shared between the Groups I-XIII is their pyrrole core. The pyrrole core of claim 1 does not present a contribution over the prior art. As disclosed in *Kawai et al* (WO 98/02430) (abstract) provided by Applicant, the pyrrole core of instant claim 1 is anticipated. As such, Group VI does not share a special technical feature with the instant claims of Group I-V and XIII. Therefore, the claims are not so linked within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I-XIII is broken.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If any of Group I-XIII is elected, the following species election is required:

- a) A single compound species recited by claims 1-14;

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, as to claims 1-14, Applicant is required to elect a single compound species from the numerous possible species for examination, and as to that species, Applicant is required to define each of R^1 - R^5 , M and every additional variable as required for that particular species (a species for example is methyl, NOT alkyl). Accordingly, upon Applicant's election of species, the result must provide a single chemical species. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species listed above in the following manner: claims 3-6, 8-12, 14 as to Group I; claims 2-6, 8-11, 14 as to Group II; claims 2-11, 14 as to Groups III and IV; claims 2-11, 13-14 as to Group V; and claims 2-14 as to Group VI. The following claim(s) are generic: claims 2 and 16 as to Groups I-VI; claim 1 as to Groups VII-XII and claims 15 as to Group XIII.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

a) each chemical species is a distinct chemical which lacks a special technical feature in view of *Kawai et al* (WO 98/02430) (abstract)

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the

requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571)270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 4161

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161